EXHIBIT 4

Inspections, Compliance, Enforcement, and Criminal Investigations

Health Breakthrough International, LLC 12/12/13

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Seattle District
Pacific Region
22215 26th Avenue SE, Suite 210
Bothell, WA 98021-4425

Telephone: 425-302-0340
FAX: 425-302-0402

December 12, 2013

OVERNIGHT DELIVERY
SIGNATURE REQUIRED

In reply refer to Warning Letter SEA 14-03

David Wheeler, Owner
Health Breakthroughs International, LLC
8196 SW Hall Boulevard, Suite 108
Beaverton, Oregon 97008

WARNING LETTER

Dear Mr. Wheeler:

The United States Food and Drug Administration (FDA) conducted an inspection of Health Breakthroughs International, LLC, located at 8196 SW Hall Boulevard, Suite 108, Beaverton, Oregon, on April 12, 16 and 18, 2013. During our inspection, the investigators found significant violations of the current good manufacturing practice (CGMP) regulations for dietary supplements, Title 21, Code of Federal Regulations, Part 111 (21 CFR Part 111). These CGMP violations cause your dietary supplement products MPS Gold 100 MPS Gold 3X, and Amazing C to be adulterated within the meaning of section 402(g)(1) of the Federal Food, Drug and Cosmetic Act (the Act) [21 U.S.C. § 342(g)(1)] in that these dietary supplements have been prepared, packed, or held under conditions that do not meet CGMP regulations for dietary supplements. Our investigators' observations were presented to you on Form FDA-483, Inspectional Observations, at the conclusion of our inspection on April 18, 2013.

Additionally, we reviewed the product labels for your MPS Gold 100 and MPS Gold 3X products, and have determined that those products are misbranded under section 403 of the Act [21 U.S.C. §§ 343] and the regulations implementing the food labeling requirements of the Act, which are found in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You may find the Act and FDA's regulations through links on the FDA's home page at www.fda.gov[1].

Dietary Supplement CGMP Violations

Our inspection revealed the following violations:

1. You did not conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient prior to its use, as required by 21 CFR 111.75(a)(1)(i), nor has the FDA received a petition from you, and granted the petition, to exempt you from this testing requirement, pursuant to 21 CFR 111.75(a)(1)(ii). Specifically, the following products and batches lacked necessary identity testing to verify components that are dietary ingredients:

Product	Dietary Ingredients	Batch Numbers
MPS Gold 100	Aloe vera power, larch powder	/2103204, $2103204, $2103205, 13103205, 13104205, 23104206, 23105206, 33106206
MPS Gold 3X	Aloe vera power, larch powder	$2103301, 13103301, 13104301, 23105301, 43106301, 43106302
Amazing C	Ascorbic acid, calcium citrate, magnesium citrate, L-Glutamine	$202, 1302

2. You failed to qualify a supplier of a component that is not a dietary ingredient by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of their tests or examinations, as required by 21 CFR 111.75(a)(2)(ii)(A). Specifically, you received and relied on a COA for NAT/ART BERRY FLAVOR POWDER and INOSITOL; however you did not first qualify the supplier throug confirmation of the results of their tests or examinations.

3. You failed to establish component specifications for each component that you use in the manufacture of a dietary supplement that are necessary to ensure that specifications for the purity, strength, and composition of the dietary supplements you manufacture using those components are met, as required by 21 CFR 111.70(b)(2). For example, between the dates of December 4, 2012, and April 6, 2013, you manufactured dietary supplements approximately **(b)(4)** times using approximately seven ingredients. However, you have not established specifications for any of the ingredients, including larch powder and Aloe vera powder that were used in the manufacturing of your MSP Gold products; and ascorbic acid, calcium citrate, magnesium citrate, and L-Glutamine that were used in the manufacturing of your Amazing C product.

4. You failed to establish specifications for the dietary supplement labels (label specifications) and for packaging that may come in contact with the dietary supplements (packaging specifications), as required by 21 CFR 111.70(d).

5. You failed to determine whether you met established product specifications for your finished dietary supplement products, as required by 21 CFR 111.73. Specifically, you have established finished dietary supplement product specifications for MPS Gold 100, MPS Gold 300, and Amazing C, in accordance with 21 CFR 111.70(e), but you have not tested any of your finished dietary supplement products for identity, strength, purity or composition, in accordance with 21 CFR 111.75(c).

6. Although you have product formulas for your Amazing C and MPS Gold products, you failed to establish and follow a written master manufacturing record (MMR) in accordance with the requirements in 21 CFR part 111, subpart H. Specifically:

a. You have product formulas, however they are not batch size specific, as required by 21 CFR 111.205(a).
b. You do not have a written description of the packaging and a representative label, or a cross-reference to the physical location of the actual or representative label, as required by 21 CFR 111.210(g).
c. You do not have written instructions for specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the MMR, as required by 21 CFR 111.205(b)(1).

d. You do not have corrective action plans for use when a specification is not met, as required by 21 CFR 111.210(h)(5).

7. You failed to prepare batch production records every time you manufacture a batch of dietary supplements, as required by 21 CFR 111.255(a). In addition, your batch production records do not include all of the required information, to comply with 21 CFR 111.260. Specifically, your firm's batch production records do not include the following:

a. The batch, lot, or control number assigned in accordance with 21 CFR 111.425(f) for each lot of packaged and labeled dietary supplement from the finished batch of dietary supplement, as required by 21 CFR 111.260(a)(2)(i).
b. The date and time of maintenance, cleaning, and sanitizing for the equipment and processing lines used in producing the batch, or a cross reference to those records, as required by 21 CFR 111.260(c).
c. Unique identifiers that you assigned to each component, packaging, and labeling used, as required by 21 CFR 111.260(d).
d. The identity and weight or measure of each component used, as required by 21 CFR 111.260(e).
e. A statement of actual yields and a statement of the percentage of theoretical yield at appropriate phases of processing, as required by 21 CFR 111.260(f).
f. An actual or representative label, or a cross-reference to the physical location of the actual or representative label specified in the MMR, as required by 21 CFR 111.260(k)(2).
g. Documentation at the time of performance that quality control personnel approved and released, or rejected, the packaged and labeled dietary supplement, including any repackaged or relabeled dietary supplement, as required by 21 CFR 111.260(l)(4).

8. You failed to implement quality control operations in your manufacturing, packaging, labeling, and holding operations for producing your dietary supplements to ensure the quality of the dietary supplement and that the dietary supplements are packaged and labeled as specified in the master manufacturing record, as required by 21 CFR 111.65. Additionally, you failed to identify a person who is responsible for quality control operations. Each person who is identified to perform quality control operations must be qualified to do so and have distinct and separate responsibilities related to performing such operations from those responsibilities that the person otherwise has when not performing such operations, as required by 21 CFR 111.12.

9. You failed to collect or hold reserve samples of packaged and labeled dietary supplement products that you have distributed, as required by 21 CFR 111.83(a).

10. You failed to quarantine components and collect representative samples of each unique lot of components before you used them in the manufacture of dietary supplements, as required by 21 CFR 111.155(c)(1). Specifically, there is no quarantine area set up for receiving ingredients.

11. You failed to establish or follow written procedures for calibrating, inspecting, and checking automated, mechanical, and electrical equipment, as required by 21 CFR 111.25(b). Specifically, there is no written procedure for calibrating the scale.

12. You failed to establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing, as required by 21 CFR 111.103. Specifically, you do not have any written quality control procedures related to reviewing and approving components, labels, packaging, or finished product for distribution.

Misbranding Violations

In addition, your MPS Gold 100 and MPS Gold 3X products are misbranded within the meaning of section 403(s)(2)(C) of the Act [21 U.S.C. § 343(s)(2)(C)] in that the product labels fail to identify the part of the plant from which a botanical ingredient is derived in the ingredient statement, as required by 21 CFR 101.4(h)(1). For example, the labels for these products state that the products contain aloe vera, but the part of the aloe vera plant from which the ingredient is derived is not identified in an ingredient

statement.

This letter is not an all-inclusive list of violations in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials for all of your products to ensure that the claims you make for your products do not cause them to violate the Act.

You should take prompt action to correct the violations described above and prevent their future recurrence. Failure to promptly correct these violations may result in enforcement action without further notice including, but not limited to, seizure and/or injunction. [21 U.S.C. §§ 332 and 334].

We also note that your MPS Gold 100, MPS Gold 3X, and Amazing C product labels state the product weight but do not use the term "net weight" or "net wt." According to 21 CFR 101.105(j)(3), the term "net weight" shall be used when stating the net quantity of contents in terms of weight.

Further, we note that although you do have a lot code system and record, the lot code is not recorded consistently and is not always included on the final product.

Section 743 of the Act (21 U.S.C. 379j-31) authorizes FDA to assess and collect fees to cover FDA's costs for certain activities, including re-inspection-related costs. A re-inspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determine whether compliance has been achieved. Re-inspection-related costs means all expenses, including administrative expenses, incurred in connection with FDA's arranging, conducting, and evaluating the results of the re-inspection and assessing and collecting the re-inspection fees (21 U.S.C. 379j-31(a)(2)(B)). FDA will assess and collect fees for re-inspection-related costs from the responsible party for the domestic facility. The inspection noted in this letter identified noncompliance materially related to a food safety requirement of the Act. Accordingly, FDA may assess fees to cover any re-inspection-related costs.

We request that you notify this office in writing, within 15 working days from your receipt of this letter, of the specific steps you have taken to correct the noted violations. Include any documentation necessary to show that correction has been achieved. If corrective actions cannot be completed within 15 working days state the reason for the delay and the time within which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: LCDR Cynthia White, Compliance Officer, 22215 26th Avenue SE, Suite 210, Bothell, Washington 98021-4425. If you have questions regarding any issue in this letter, please contact LCDR White at (425) 302-0422.

Sincerely,
/S/
Gerald D. Bromley Jr.
Acting District Director

cc: Oregon Department of Agriculture
Food Safety Division
635 Capitol Street NE
Salem, Oregon 97301

Page Last Updated: 03/04/2014
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
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Contact FDA

Links on this page:

1. http://www.fda.gov/